

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Dean A. Klein et al.	Examiner: MEHTA, Parikha
Appln. No.: 10/626,931	Group Art Unit: 3737
Filing Date: July 25, 2003	Confirmation No.: 5405
Title: MULTI-MODALITY MARKING MATERIAL AND METHOD	Customer No.: 25764 Docket No.: 54459 - 277675

SECOND DECLARATION OF DEAN A. KLEIN UNDER 37 C.F.R. 1.132

I, Dean A. Klein, declare and state the following:

1. I am a joint inventor on the above-reference patent application no. 10/626,131 ("the '131 application").
2. I am the sole inventor of U.S. Patent 6,394,965 ("the '965 patent").
3. As part of my attempt to develop a commercial embodiment of the invention described in the '965 patent, an experiment was conducted to determine whether a plurality of microparticles including a zirconium oxide substrate and a carbon coating were sufficiently detectable using x-ray imaging techniques to be used as a tissue marker at an anatomical tissue site.
5. The results of these experiments indicated that the microparticles were detectable under x-ray imaging, but were not visually distinguishable from certain features of anatomical tissue sights such as microcalcifications often contained in soft tissue such as breast tissue.

6. An embodiment of a marker within the scope of the '965 patent claims was not commercialized.

7. In contrast, the marker described and claimed in the '131 application is sized and shaped such that it is distinguishable from features of the anatomical site under multiple imaging modalities, including x-ray (e.g., mammography), ultrasound and magnetic resonance imaging. An unexpected benefit of the marker is that, as demonstrated in the examples of the '131 application, it is detectable under magnetic resonance imaging without substantial distortion as compared to several commercially available tissue markers.

8. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of any patent issued from U.S. Patent Application No. 10/626,131.

Respectfully Submitted,



Dean A. Klein

Dated: March 26, 2008